

Claims

1. A pharmaceutical composition comprising a basic drug compound, a surfactant and a physiologically tolerable water-soluble acid characterized in that the acid:drug

5 compound ratio is at least 1:1 by weight;

or

comprising an acidic drug compound, a surfactant and a physiologically tolerable water-soluble base characterized in that the base:drug compound ratio is at least 1:1 by weight.

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2. A composition according to claim 1 comprising a basic drug compound, a surfactant and a physiologically tolerable water-soluble acid characterized in that the acid:drug compound ratio is at least 1:1 by weight.

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3. A composition according to claim 1 or 2 characterized in that the physical state of said composition is a solid dispersion.

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4. A composition according to any one of claims 1 to 3 wherein the acid is selected from the group comprising citric, fumaric, tartaric, maleic, malic, succinic, oxalic, malonic, benzoic, mandelic and ascorbic acid.

5. A composition according to any one of claim 4 wherein the acid is citric acid.

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6. A composition according to any one of claims 1 to 5 further comprising an organic polymer.

7. A composition according to 6 wherein the polymer is selected from the group comprising

- alkylcelluloses such as methylcellulose,
- hydroxyalkylcelluloses such as hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and hydroxybutylcellulose,
- hydroxyalkyl alkylcelluloses such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose,
- carboxyalkylcelluloses such as carboxymethylcellulose,
- alkali metal salts of carboxyalkylcelluloses such as sodium carboxymethylcellulose,
- carboxyalkylalkylcelluloses such as carboxymethylethylcellulose,

-128-

- carboxyalkylcellulose esters,
- starches,
- pectins such as sodium carboxymethylamylopectin,
- chitin derivates such as chitosan,
- 5 - heparin and heparinoids,
- polysaccharides such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, tragacanth, agar-agar, gum arabic, guar gum and xanthan gum,
- polyacrylic acids and the salts thereof,
- 10 - polymethacrylic acids and the salts thereof, methacrylate copolymers,
- polyvinylalcohol,
- polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate,
- polyalkylene oxides such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide, e.g. poloxamers and
- 15 - poloxamines.

8. A composition according to claim 6 or 7 wherein the polymer has an apparent viscosity of 1 - 100 mPa.s when dissolved in a 2% aqueous solution at 20°C.

20 9. A composition according to any one of claims 6 to 8 wherein the polymer is hydroxypropylmethylcellulose.

10. A composition according to claim 6 or 7 that provides sustained release of the drug, characterized in that it comprises a water soluble polymer having an apparent viscosity of more than 1,000 mPa.s when dissolved in a 2% aqueous solution at 20°C.

25 11. A composition according to any one of the preceding claims wherein the surfactant is an alcohol-oil transesterification product.

30 12. A composition according to claim 11 wherein the surfactant is cremophor RH 40 or Vitamin E TPGS.

13. A composition according to any one of the preceding claims wherein the drug compound is no more than sparingly soluble in water.

35 14. A composition according to any one of the preceding claims wherein the drug compound is selected from

4-[[4-[[4-(2-cyanoethenyl)-2,6-dimethylphenyl]amino]-2-pyrimidinyl]amino]-benzonitrile;

4-[[2-[(cyanophenyl)amino]-4-pyrimidinyl]amino]-3,5-dimethylbenzonitrile;

4-[[4-[(2,4,6-trimethylphenyl)amino]-2-pyrimidinyl]amino]benzonitrile;

5 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenoxy)-2-pyrimidinyl]amino]-benzonitrile;

a *N*-oxide, an addition salt, a quaternary amine and a stereochemically isomeric form thereof.

10 15. A pharmaceutical dosage form comprising a therapeutically effective amount of a pharmaceutical composition as defined in any one of the preceding claims.

16. The dosage form of claim 15 adapted for topical administration or administration into an externally voiding body cavity such as the nose, lungs, mouth, ear, stomach,

15 rectum and vagina.

17. The dosage form of claim 15 wherein said composition is filled into a standard capsule, or alternatively is mixed with bulking agents and compressed into tablets.

20 18. A pharmaceutical composition according to any one of claims 1 to 14 for use in the manufacture of a pharmaceutical dosage form for oral administration to a mammal in need of treatment, characterized in that said dosage form can be administered at any time of the day independently of the food taken in by said mammal.

25 19. Use of a pharmaceutical composition according to any one of claims 1 to 14 for the manufacture of a pharmaceutical dosage form for oral administration to a mammal in need of treatment, characterized in that said dosage form can be administered at any time of the day independently of the food taken in by said mammal.

30 20. A pharmaceutical package suitable for commercial sale comprising a container, an oral dosage form as claimed in any one of claims 15 to 17, and associated with said package written matter non-limited as to whether the dosage form can be administered with or without food.